

Appln. No. 09/756,185

Supp. Amdt. dated August 27, 2004

Reply to Office action of December 17, 2003

REMARKS

Claims 3, 11-16, 19-21 and 23-25 presently appear in this case. No claims have been allowed. Consideration of the present supplemental amendment in conjunction with applicant's supplemental response of July 19, 2004, and applicant's amendment of March 17, 2004, and reconsideration and allowance are respectfully urged.

Following a telephone conference with Examiner Mitra on or about August 23, 2004, Examiner Mitra unofficially forwarded a proposed examiner's amendment to the undersigned by fax, in order to suggest language that would place the case into condition for allowance. On August 25, 2004, the undersigned contacted the examiner by telephone to discuss the proposed amendment, and Examiner Mitra suggested that I speak to her supervisor, Mr. Weber, about our questions as to why certain amendments were made in these claims.

In a subsequent telephone conference with Mr. Weber, the undersigned inquired as to why the claims were proposed to be amended to specify that the growth factor was either bFGF or VEGF. Mr. Weber explained that when a patent is being allowed because of a showing of unexpected results, the showing must be commensurate in scope with the claims, and this is why he wanted the claims to be specifically directed

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to the human growth factor being either bFGF or VEGF.
Applicant accepts this proposed amendment to the independent claims without prejudice to the continuation of prosecution of broader claims in a continuing application.

The examiner was then asked why the method claims needed to be amended so as to only read on the administration of a single composition containing both components, particularly in view of the fact that the present specification at page 2, lines 29-30, indicates that the two active compounds are preferably administered by two pharmaceutical preparations, each containing separately one of the two ingredients. Mr. Weber indicated that the issue is the temporal relationship. He stated that the claims do not explain how soon after administration of one must the other be administered.

In order to avoid this issue of temporal relationship, and still have the claims cover applicant's preferred embodiment of administering the components in separate preparations, applicant proposes to amend the independent method claims to specify this temporal relationship. In this regard, it should be noted that page 2 of the specification, lines 9 and 10, state that the invention relates to "the simultaneous presence of CB and a growth

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factor". This presents a temporal requirement without the necessity of both being mixed in a single composition dosage form. Furthermore, at page 2, lines 25-27, it says that any route of administration may be used that establishes "the desired blood levels of respective active agents." The following paragraph states that it is preferred that two pharmaceutical preparations be administered, each containing separately one of the two ingredients. Accordingly, there is support in the specification for the concept that the components can be administered in any way that permits the simultaneous presence of CB and growth factor in the bloodstream. In light of this disclosure, the independent method claims have now been amended to insert at the end:

, whereby said Component B and said human growth factor are administered such that they will be simultaneously present in the blood of the patient in amounts effective for the promotion of angiogenesis in the patient.

For the reasons discussed above, this concept appears in the specification, and thus this proposed amendment fully complies with the written description requirement of the first paragraph of 35 U.S.C. §112. As this language obviates the examiner's concern about the temporal relationship of administration, these claims should be allowed without the

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necessity of requiring that the Component B and growth factor be administered in a single composition.

In the telephone interview, the undersigned asked Examiner Weber why he required the removal of the word "synergistic" in claims 19, 24 and 25, and why the examiner required applicant to specify the ratio of the amount of Component B to the amount of the human growth factor in these claims. Examiner Weber stated that he does not like to see the word "synergistic" in claims, as this suggests that the results are unexpected, and if they are unexpected, how can they be claimed. He further stated that, without a ratio it would take undue experimentation to determine what results are unexpected. I explained to the Mr. Weber that his use of the word "unexpected" was inappropriate in this context, as the results were only unexpected prior to the present invention. Anyone of ordinary skill in the art reading the present specification would be taught that these synergistic results are obtainable and, thus, they are now expected. It would not involve undue experimentation for anyone of ordinary skill in the art to measure the effect of Component B, and consider that to be X amount of activity, to measure the activity of human growth factor, and consider that to be Y amount of activity, and determine whether any combination of the two

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provides activity greater than $X + Y$. There is nothing unexpected involved in that test, and it is a simple and straightforward test that would not require undue experimentation. Therefore, there should not be the necessity of having any ratio in the claim, as the ratio is functionally described as being synergistic.

Examiner Weber stated that he understood this argument, and that he would take it under advisement. Applicant hereby repeats this explanation, and requests that the requirement to remove the word "synergistic" from these claims and to insert certain ratios be withdrawn.

The present amendment accepts all of the other proposed claim amendments set forth in the informal fax, except in claims 23 and 25, the proposed addition of the word "angiogenesis" has been omitted, as these claims are directed to treatment of a wound, ulcer or other traumatic lesion, and do not use the term "angiogenesis". It is believed that the term "synergistic results" in context in these claims is sufficient, and it is not necessary to be concerned about antecedent basis for the new word "angiogenesis".

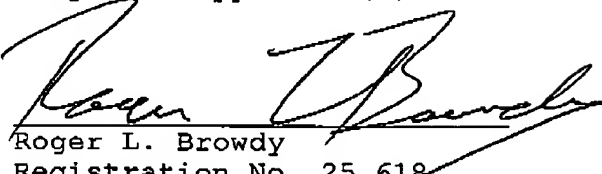
If the present proposal is not fully acceptable to Examiner Mitra and Supervisor Weber, it is respectfully requested that the undersigned be contacted by telephone in

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order to reach agreement on exactly what wording would be acceptable to both sides in order to place the case into condition for allowance. It is urged, however, that the wording presented herewith fully complies with 35 U.S.C. §112, and clearly defines over the references of record. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,
BROWDY AND NEIMARK, P.L.L.C.
Attorneys for applicant(s)

By

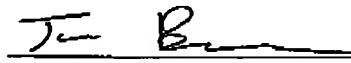

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this supplemental amendment is being facsimile transmitted to the Patent and Trademark Office, on the date shown below.

Jonathan Brammer
Name


Signature

August 27, 2004
Date